Chapter 20

RESEARCH AND DEVELOPMENT

Sections

20-1. Policy

(1) The fundamental policy of the Navy Medical Department encourages and supports research and development (R&D) in medical, dental, nursing, and allied sciences. This R&D is directed at the solution of problems affecting the health, safety, selection and efficiency of Navy and Marine Corps personnel.

20-2. Departmental Responsibilities

(1) General.-The Assistant Secretary of the Navy for Research, Engineering and Systems (ASN (RE&S)), under direction of the Secretary of the Navy, exercises responsibility for Department-wide supervision of all research, development, engineering, testing, evaluation of efforts, and appropriations management. The principal advisors for support and assistance are: The Director of Research, Development, Test and Evaluation (RDT&E) for the Chief of Naval Operations; the Deputy Chief of Staff, Research, Development and Systems (RD&S), Marine Corps; the Chief of Naval Research; the Chief of Naval Technology; the Commander, Naval Medical Command; and SECNAV-Designated Project Managers. The interpretation and promulgation of DOD policies and procedures by the Secretary of the Navy or ASN (RE&S) provide the framework for planning and implementing the RDT&E program. Full responsiveness of the RDT&E program to Navy needs is ensured through the coordination of the above prinicipal advisors (SECNAVINST 5430.67 series).

(2) Medical Department.- Under the policy guidance of the Director, Naval Medicine and the direction of the Naval Medical Command, the management and coordination of the RDT&E programs of the Medical Department of the Navy are the responsibility of the Naval Medical Research and Development Command (NMRDC).

(3) Naval Medical Command.

(a) The Deputy Commander for Fleet Readiness and Support is responsible for the overall management of Research and Development matters. The Naval Medical Command:

(1) Identifies, defines, and communicates requirements for medical RDT&E consistent with higher authority.

(2) Assesses and oversees the RDT&E programs to ensure responsiveness to defined requirements.

(3) Monitors and coordinates Medical Department responsibilities concerning the use and protection of human subjects utilized in studies conducted under the auspices of the Department of the Navy.

(4) Exercises command responsibility over the Naval Medical Research and Development Command.

(4) Naval Medical Research and Development Command (NMRDC).-

(a) The Commanding Officer of the Naval Medical Research and Development Command serves as an advisor to the Director, Naval Medicine and Commander, Naval Medical Command.

(b) The direct management and coordination of the Navy Medical Department RDT&E program is carried out by the Naval Medical Research and Development Command.

The Naval Medical Research and Development Command:

(1) Commands and provides mission support for the Navy Medical Department research and development laboratories and activities.

(2) Directs, plans, programs, budgets, and documents Navy Medical Department RDT&E efforts in response to Navy and Marine Corps RDT&E requirements.

(3) Recommends the qualifications, procurement, training, assignment, and distribution of research and development personnel.

(4) Provides professional medical and dental technical guidance in the planning of Navy and Marine Corps RDT&E on weapons systems, life support systems and personnel protection.

(5) Coordinate research efforts with other Navy commands and offices, other Government agencies, civilian organizations, and foreign governments.

20-3. Scope

(1) Medical Department research and development programs shall be organized to support Navy, Marine Corps, and Medical Department missions and shall be directed toward improving and protecting the health and performance effectiveness of Navy and Marine Corps personnel in operational environments.

(2) Medical Department research, development, testing, and evaluation (RDT&E) shall address medical requirements promulgated by the Chief of Naval Operations, the Commandant of the Marine Corps, the Chief of Naval Research and the Chief of Naval Technology, following validation by the Director, Naval Medicine. To meet these requirements and objectives, a broad program of RDT&E shall be maintained in the basic and applied sciences, with major emphasis placed on problems of combat casualty care, performance effectiveness, decompression sickness and diver health, disease prevention and control, and occupational hazards in naval environments.

20-4. Professional Personnel Assignments

(1) The Navy Medical Department sponsors research programs in aviation medicine, diving medicine, submarine medicine, fleet health care, fleet occupational health, infectious diseases, oral and dental health, human performance, and electromagnetic radiation. Research efforts under these programs are conducted at U.S. Navy medical research laboratories located within the contiguous U.S., as well as at selected overseas locations. Personnel of the Medical Corps, Dental Corps, Medical Service Corps, and Nurse Corps are encouraged to contact their appropriate detailers regarding assignment possibilities within the Navy biomedical research and development community. Qualified personnel will be given guidance and aid in securing assignments, contingent upon availability of billets and requirements in given programs.

20-5. Program Management

(1) Structure.-The technical and administrative management of medical RDT&E is accomplished within the planning, programming, and budgeting system. Under this system, RDT&E is categorized under DOD Program VI, Research and Development, and is divided into five broad categories: 1-Research, 2-Exploratory Development, 3-Advanced Development, 4-Engineering Development, and 5-Management and Support.

(2) Categories.- Programs are conducted under the following categories:

(a) Category 1, Research, includes efforts directed toward enhanced knowledge of medical and behavioral sciences, and the solution of problems associated with these sciences. It provides the base for subsequent exploratory and advanced development.

(b) Category 2, Exploratory Development, includes efforts directed toward the solution of specific military problems, short of major development projects. This type of effort may vary from fundamental applied research, to minor development efforts. The dominant characteristic of this category is that it addresses specific military problems with a view toward developing and evaluating the feasibility and practicability of proposed solutions.

(c) Category 3, Advanced Development, includes efforts relating to the design of equipment, materials, or procedures for subsequent test and evaluation, but does not necessarily assure their operational usefulness, technical feasibility, or financial acceptability.

(d) Category 4, Engineering Development, includes those projects being engineered for service use but that have not yet been approved for procurement or operation. Efforts in this category will include a determination of operational usefulness, acceptability, and cost.

(e) Category 5, Management and Support, provides facilities and installation support for research and development activities, and managerial and planning support at NMRDC. This category provides funds for the indirect cost of research and development and other laboratory costs not directly related to specific research efforts. Included are costs for operation and maintenance, minor

construction and alteration, administratives upport, and general purpose scientific equipment.

(3) Projects and Task Areas.- Projects, task areas, and tasks for medical RDT&E will be established in a manner consistent with the requirements specified in paragraph 20-3(2) above.

(4) Work Units.-Work units under the above projects, task areas, and tasks will be assigned either to activities directly by NMRDC or as approved research and development proposals submitted by the activities.

(a) Proposals for Navy medical RDT&E support shall be submitted to NMRDC by the performing activities.

(b) Proposals shall be submitted on the Research and Technology Work Unit Summary, DD Form 1498, in accordance with DOD Directive 3200.12 series and annual implementing guidance provided by NMRDC.

(c) The selection and approval of medical RDT&E proposals will be based on program objectives and operational requirements, immediacy of need, operational impact, experience and competence of the investigators, scientific merit, availability of facilities and funds, and probability of success, level of effort outside the Navy, and the special opportunities that may be offered by the location and environment of particular facilities. Programs are reviewed systematically by in-house scientific advisory committees and NMRDC program managers, and by the Joint Technology Coordinating Groups of the Armed Services Biomedical Research Evaluation and Management Committee. A variety of ad hoc mechanisms are also employed, including but not limited to external peer review groups, technical workshops and program or resources sponsor reviews.

(5) Reporting Requirements.-

(a) Management Reports.-NMRDC requires regular progress reports on work units under its management responsibility. Interim progress reports are required annually on all active work units. Final reports are required at the earliest practicable time on completion or termination of work units.

(b) Technical/Scientific Reports.-

(1) In accordance with SECNAVINST 3900.29 series, a DD Form 1473, Document Control Data-R&D, shall be completed and included as the last page of each copy of all technical/scientific reports, including those submitted in reprint form. The instruction sheet that is attached to DD Form 1473 should be consulted for information about preparation of the form.

(2) Twelve copies of unclassified technical/scientific reports shall be submitted to the Defense Technical Information Center (DTIC) accompanied by a DTIC Form 50. All copies of reports submitted shall include an appropriate distribution statement in accordance with NAVMATINST 5200.29 series. Three copies of all technical/scientific reports shall also be submitted to NMRDC. Reproduction of published articles will conform to existing Federal copyright laws and regulations.

(3) Technical/scientific reports shall be classified in accordance with OPNAVINST 5510.1 series, Department of the Navy Information Security Program. A recommended distribution list for each classified report shall be submitted to NMRDC for review and approval prior to distribution.

(4) To ensure uniform compliance with established Navy policy and security regulations, all medical R&D technical/scientific reports, speeches, and any other material planned for public dissemination, shall be cleared by the commanding officer of the performing activity and should be consistent with current guidance provided by article 1116 of NAVREGS and OPNAVINST 5510.1 series in reviewing material for public disclosure. If a clearance determination cannot be made at the command level, the material should be submitted to NMRDC for review and decision.

20-6. Independent Research Program

(1) Objective.-The principal objective of this program is to enable laboratories to expand basic research capabilities. Through this program, highly competent investigators are encouraged to initate new and challenging work that may ultimately enhance regular laboratory programs or lead to innovative long-term efforts.

(2) Funds.-Subject to the current availability of funds, NMRDC will provide Navy medical RDT&E laboratories with funds to conduct independent research. These funds, being allocated in addition to those used to support other approved or assigned work units, will provide flexibility for the investigation of new ideas generated during the year. Primarily, independent research funds are to augment technical competence and be used for work that has clear Navy relevance. These funds shall not be used to compensate for other approved programs' deficits or as a substitute for previously rejected research proposals.

(3) Controls.-NMRDC approval is required for research undertaken with these funds, but projects are initiated by investigators and should address innovative new work that has Navy relevance. This research must conform to the policy guidance indicated in (20-7) and (20-8).

Research projects will have a 3-year limitation, after which the research will be considered completed, terminated, or appropriate for funding in other research programs.

(4) Management Reports.-Annual progress reports on work sponsored under the Independent Research Program shall be submitted in accordance with NAVMATINST 3920.3 series and specific guidance issued annually by NMRDC. A DD 1498 ("NEW") will be forwarded to NMRDC for assignment of a work unit number and submittal to the Defense Technical Information Center.

20-7. Use of Human Volunteers in Medical Research

(1) Authority.-SECNAVINST 3900.39 series prescribe Navy policies and procedures governing the use of human volunteers in RDT&E projects. These instructions shall be followed for any medical research and development efforts involving use of human volunteers.

(2) Records.-Medical research documentation and records must be filed and retained in accordance with the provisions of SECNAVINST 3900.39 series.

20-8. Use of Animals in Medical Research

(1) Authority.-DOD Directive 3216.1 series and implementing SECNAVINST 3900.38 series establish policies and procedures governing the responsible use, humane care, and review of the use of animals in RDT&E programs. These instructions shall be followed for any biomedical research and development efforts involving the use of animals.

(2) Personnel and Technical Assistance.-BUMEDINST 6401.1 series delineates the policies governing military veterinary medical support for Naval activities. SECNAVINST 3900.38 series assigns NAVMEDCOM the responsibilities of coordinating and overseeing the use of animals by the Naval Establishment, and the Assistant for Veterinary Medicine (Code 02E) NAVMEDCOM, will provide specialized assistance as needed.

20-9. Use of Investigational Items Under Federal Food and Drug Administration Control

(1) Authority for Navy Medical Department activities or contractors supported by the Navy Medical Department to conduct clinical, laboratory, or field trials of drugs or biologicals covered by the Federal Food, Drug, and Cosmetic Act must be obtained from NAVMEDCOM in accordance with the provisions of NAVMEDCOMINST 6710.4 series.

(2) Compliance with SECNAVINST 3900.39 series is also required when human volunteers participate in Navy Medical Department-sponsored RDT&E investigations using FDA-controlled materials.

20-10. Resident Associateships

(1) NMRDC, in cooperation with the National Research Council, National Academy of Sciences, and the National Academy of Engineering, offers numerous opportunities for postdoctoral research to qualified civilian biomedical scientists and bioengineers in areas of major concern to the scientific and technological community. Within the fields of aerospace, submarine, diving, preventive medicine, oral health, and the behavioral sciences, NMRDC scientists seek to define potential medical hazards facing man in naval systems, and to devise methods and procedures to counteract them; thus ensuring maximum effectiveness in underwater, surface, and aerospace environments.

(2) Resident Research Associateship awardees may be offered appointments by the National Research Council (NRC). Award applications will be received by the NRC Associateship Office and evaluated on a competitive basis by special NRC panels of scientists and engineers. Each applicant is responsible for formulating a specific research plan on a problem related to NMRDC current program interest, and which program the applicant wishes to investigate. Individuals having research interests relating to one or more of the opportunities described in this chapter are advised to communicate directly with NMRDC for further information.